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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,861	04/25/2001	Daniel Dupret	58763.000013	4902

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/840,861	Applicant(s) DUPRET ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 50-92 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,50-73,75,77,79,80,82,86,90 and 92 is/are rejected.
- 7) ☒ Claim(s) 74,76,78,81,83-85,87-89 and 91 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

In careful reconsideration of the finality of the rejection of the last Office action, the finality of that action is withdrawn.

Therefore, the instant Office Action supersedes all rejections and objections made in the previous Office Actions.

Preliminary Remark

In attempts for compact prosecution, the attorney of record, Mr. Robert Schulman, had been contacted on April 5, 2004. No agreement had resulted from said contact, resulting in the instant Office Action.

Claim Objections

Claim 72 objected to because of the following informalities: Applicants are advised to change the phrase, "recombinant polynucleotide formed by the method does not exist in nature," to the phrase, "recombinant polynucleotide formed by the method is a non-naturally occurring polynucleotide." Since the claimed method would produce a recombinant polynucleotide, such would necessarily exist. It appears that the suggested claim language would better characterize the invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51, 59, 68, 82, 86, and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 is indefinite for the recitation of the phrase, "the hybridization step is repeated...until the ends of at least a *majority* of the hybridized fragments are immediately adjacent to each other," because the metes and bounds of the term, "majority" is not clearly defined in the specification and therefore, it becomes unclear how many fragments are considered to be a majority.

Claim 59 is indefinite for the recitation of the phrase, "fragments that have been obtained in a controlled manner," because it is unclear what process is embraced by the term, "controlled manner," rendering the fragments that are produced by this process indefinite in their metes and bounds.

Claims 68 and 90 are indefinite for the recitation of the phrase, "the highest temperature at which the steps of the method are conducted," because the specification does not define a clear basis of temperature range on which the method is conducted. Since the term, "highest temperature," varies on what temperatures are employed in the method, such term would be indefinite in its metes and bounds.

Claim 82 is indefinite for the recitation of the phrase, "after the selecting step, choosing at least one recombinant polynucleotide sequence formed at the ligating step," because it is unclear whether the "chosen" at least one recombinant polynucleotide sequence is the selected polynucleotide sequence which exhibit "advantageous characteristics" as described in claim 81, or any recombinant polynucleotide sequence formed after the ligating step.

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Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 86 recites that the selected recombinant polynucleotide sequence which exhibit advantageous characteristic (as described in claim 81) is, "used to select further recombinant polynucleotide sequence formed during a subsequent operation of the method," but fails to recite what step is involved in such selection, thus failing to recite the essential step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 50-73, 75, 77, 79, 80, and 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Pachuk et al. (U.S. Patent No. 6,143,527, issued November 7, 2000, filed May 6, 1997).

Pachuk et al. disclose an invitro method of using a thermostable ligase to hybridize two heterologous nucleic acid fragments adjacently to each other onto a bridging oligonucleotide (or assembly matrix), wherein the two adjacently hybridized nucleic acid fragments are ligated (column 4, line 52 through column 5, line 24; also Figure 1A), rendering instant claims 1, 51, 52, 55, 68, 92, and 79 anticipated. Applicants are advised that preamble of the instant claim has not patentable weight as all of the recited the steps are disclosed in the method of Paschuk et al.

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Additionally, the term, "heterologous," is defined in the instant specification as, "two sequences whose base composition differs by at least one base." [0073]. As the method of Paschuk et al. employs two nucleic acids of at least a single different base, rendering this limitation anticipated.

Figure 1A evidences at least one repetition of providing, hybridizing or the ligating step, anticipating instant claims 50 and 70.

Pachuk et al. employ a polymerase in filling in the gaps between the two heterologous nucleic acids, followed by the their ligation (Figure 9A through 9C), rendering instant claim 53 anticipated.

Paschuk et al. disclose an embodiment of the method, wherein the two heterologous nucleic acids are located immediately adjacent to each other, hence not needing a polymerase to fill-in the gaps therebetween (Figure 1A), thereby anticipating instant claim 54.

Paschuk et al. disclose that the two heterologous are generated by various methods such as restriction enzyme digestion fragment, DNase digestion, chemical cleavage, enzymatic or chemical synthesis (Abstract), anticipating instant claims 56-61, 71, and 75).

Figure 10A and 10B disclose that the method is employed to generated chimeric kanamycin resistance gene by recombination of gene sequence from pUC4K, the coding region from ant(4')-Ia gene in pUB110 to generate a recombinant gene disclosed by Figure 10B, rendering instant claims 62-65, 69, 72, 73, 77 anticipated.

The embodiment of the two double stranded heterologous nucleic acids first being denatured prior to the ligation-mediated assembly is also disclosed by Paschuk et al. (column 8, lines 56-59), rendering instant claims 66, 67, and 80 anticipated.

Therefore, Paschuk et al. anticipate the invention as claimed.

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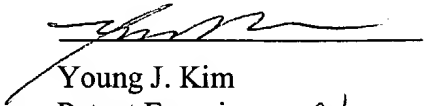
Conclusion

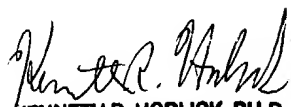
Claims 1, 50-73, 75, 77, 79, 80, 82, 86, 90, and 92 are rejected.

Claims 74, 76, 78, 81, 83-85, 87-89, and 91 are objected to for being dependent on a rejected base claim.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.


Young J. Kim
Patent Examiner
Art Unit 1637
5/3/04


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/5/04